REMARKS

The Office Action does not set a shortened statutory period for response; however, Examiner Jaworski confirmed to the undersigned on March 5, 1997 that the three month shortened period applied. A petition for a one month extension of time to file this amendment is submitted herewith.

Claims 1-17 and 19-23 are pending.

Claim 1 has been amended to incorporate the subject matter of Claim 18 which was indicated as being allowable if rewritten in independent form and to overcome the rejection of Claim 1 under 35 USC § 112. Claim 15 was also indicated as being allowable if rewritten to overcome the rejections under 35 USC § 112 and to incorporate all the limitations of the base claim and any intervening claims. Accordingly, Claim 15 has been amended to incorporate the limitations of Claims 1 and 14 from which it depended, except for the unnecessary recitation of "passive" modifying fiducial. Claims 16 and 17, which depend from Claim 15 are therefore also presented in allowable form. The unnecessary modifier "passive" has also been deleted from Claim 16.

A new Claim 22 has been added which is similar to Claim 1 except that it calls for a single camera and for processing means which comprising means responsive to actual shape, appearance and lighting conditions of at least one fiducial in the image represented by digital image signals to determine successive positions of the fiducial and means tracking three-dimensional movement of the at least one fiducial from those successive positions.

Claim 23 is a new independent claim similar to original Claim 1 but calling for the means responsive to actual shape, appearance and lighting conditions of the at least one fiducial in the digital image to determine successive positions of the at least one fiducial at a rate of at least 20 Hz.

Applicants thank the Examiner for pointing out the inadvertent error in the wording in the specification which has now been corrected.

REJECTIONS UNDER 35 USC § 112

Claims 1-21 were rejected under 35 USC § 112, second paragraph as being indefinite. The claims have been amended to address the indefiniteness issues raised by the Examiner and now satisfy the requirements of the Statute.

REJECTIONS UNDER 35 USC § 103

Claims 1-6 and 8-12 were rejected under 35 USC § 103 as being unpatentable over *Neely, et al.* (USP 5,214,711).

Neely is directed to a method for determining displacement of a body part and particularly parts of the face. Video images of the body part to be analyzed are recorded for a reference or control position and for a changed position. Repetitive images of the control and the changed position can be recorded to provide the operator with a number of images from which to select images for processing. Column 3, line 66 to Column 4, line 10. The recorded video images are digitized. The patient's head is held in a rigid position when the images are being made. Column 160, line 46 to Column 161, line 3. When it is desired to analyze the images, the stored digital signals are reconverted to analog form for presentation on a monitor. Column 4, line 28+. The operator selects the control frame to be used and also one or more changed frames. A processor then subtracts the digital image of each of the changed frames from the digital image of the control frame. This compare frame highlights the areas of the two images which are different indicating displacement of that part of the image. The operator then must manually select an area of interest. Column 10, lines 10-15. The remaining frames are designated move frames and the processor compares each of the move frames with the control frames. The change in position is quantified in terms of brightness of the subtracted image. (Subtraction eliminates areas of the two images where there is no movement and they are therefore the same.) This can be accomplished for instance by pixel counting or by integration of the pixel gray values in the area of interest in the comparisons of the changed frames with the control frame. Column 9, lines 5-22. Determination of movement of a region of interest in *Neely, et al.* is an off-line, slow process which requires a great deal of operator input. The process taught by *Neely, et al.* does not track movement, but provides a quantitative measurement of change in position of regions of interest between individual "change" images and a common control image.

Claim 1 has been amended to include the limitations of Claim 18 which has been indicated as being allowable. Claim 22 calls for apparatus responsive to movement of a patient which includes a single camera means

generating digital image signals representing an image of at least one fiducial on a patient, and processing means including means responsive to actual shape, appearance and lighting conditions of the at least one fiducial in the image to determine successive positions of the fiducial and means tracking three-dimensional movement of the at least one fiducial from the successive positions.

Neely, et al. does not provide real time tracking of movement of fiducial on a patient. It provides static measurements of changes in displacement of manually selected areas of interest in one or more static images compared to a control static image. Furthermore, it only measures two-dimensional displacement. The system of Claim 1 uses the shape and appearance of a fiducial to determine three-dimensional movement using a single camera. Hence, Claim 22 patentably distinguishes over *Neely, et al.*

Claims 8-12 all depend from Claim 22 and therefore are patentable over *Neely* for the same reasons. Furthermore, Claim 8 calls for means applying multiple levels of filtering to the digital image signals to determine successive positions of the at least one fiducial. As discussed above, *Neely, et al.* does not determine successive positions but makes quantitative measurements between selected images and a control image. Claims 9-11 call for several types of filtering applied at the multiple levels to determine the successive positions of the at least one fiducial. *Neely, et al.* utilizes filtering to remove artifacts and to equalize the images. Claim 12 calls for the processing means to include means using multiple levels of resolution to determine successive positions of the at least one fiducial and means applying multiple levels of filtering at each of the multiple levels of resolution. *Neely, et al.* does not suggest using multiple levels of resolution to determine successive positions of a fiducial, let alone applying multiple levels of filtering at each level of resolution. Accordingly, Claims 8-12 further patentably distinguish over *Neely, et al.*

Claim 23 is also a new independent claim which calls for, *inter alia*, processing means comprising means responsive to actual shape, appearance and lighting conditions of at least one fiducial to determine successive positions of the fiducial at a rate of at least 20 Hz, means tracking movement of the at least one fiducial from the successive positions, and means generating an output in response

to predetermined values of this movement. The apparatus recited in Claim 23 provides position updates of the at least one fiducial at a rate of 20 times per second and for tracking movement of the at least one fiducial from these repetitive position updates. Thus, the claimed apparatus provides real time tracking of patient movement and is novel in providing such tracking at a realistic rate which allows it to be used to automatically determine movement of a patient during treatment or diagnosis. The system of *Neely, et al.* does not provide tracking. As mentioned, it only provides measurements of movement between static images. Furthermore, it requires repeated decision making and input by the operator which clearly cannot be accomplished at 20 Hz. The numerous inputs required by the operator are discussed in *Neely* at Column 160, line 46 to Column 164, line 30. Thus, Claim 23 is not obvious in view of *Neely, et al.*

Claims 2-6 all depend from Claim 23 and are therefore patentable over the reference for the same reasons.

Claim 6 calls for means for repetitively detecting movement associated with patient breathing and random movement, and means indicating the random movement. It is suggested in the rejection that random or breathing associated with facial movements "might figure" into *Neely's* assessment "for example a patient might purse lips to blow test the orbis orbicularis strength in lieu of smiling." First, this is pure speculation. Second, movement of the lips is not an indication of breathing. Third, *Neely* suggests nothing to distinguish periodic movement associated with breathing from random movement as called for in Claim 6. Accordingly, Claim 6 further patentably distinguishes over *Neely*.

Claims 1-6 were also rejected under 35 USC § 103 as being unpatentable over *Gerig, et al.* (USP 5,446,548).

Gerig, et al. is directed to a patient positioning and monitoring system which computes the absolute position of orientation of a patient in a given frame of reference. It uses commercially available infrared laser sources attached to the wall. The radiation from the laser sources is spread by lenses so as to illuminate the retro-reflective markers attached to the patient. It uses stereovision, photogrammetry and a knowledge-base to determine the precise position information (position and orientation of the human body upper torso), in the iso-center frame of reference.

Stereovision requires two cameras which are used to triangulate position. The knowledge-base used in the computation involves calibration information of the two wall mounted cameras. The accuracy of the calibration depends heavily on information about the environment known *apriori*.

As discussed above, Claim 22 calls for apparatus for determining patient position which requires only a single camera. Two cameras are shown in the disclosure because the primary camera is mounted on the gantry which can at times be rotated below the patient positioning table and therefore not have a clear line of sight to the fiducials. At these times, the second camera such as one fixed to the ceiling over the patient is used. Of course, the field of view of the ceiling camera is blocked at times by the gantry. In any event, at any particular time a single camera is all that is required to track three-dimensional movement of the at least one fiducial. The apparatus of Claim 22 does not require the extensive calibration required by *Gerig, et al.* because unlike *Gerig, et al.* it tracks the movement of the patient rather than the absolute position. Accordingly, Claim 22 is patentable over *Gerig, et al.*

Claim 23 calls for a patient positioning system which includes, *inter alia*, means responsive to actual shape, appearance and lighting conditions of at least one fiducial to determine successive positions of at least one fiducial at a rate of at least 20 Hz. As discussed, *Gerig, et al.* uses stereo triangulation to determine absolute position and not the actual shape, appearance and lighting conditions to determine successive positions. Furthermore, the system of *Gerig* is very slow. Coordinates of the targets on the patient are measured only every five seconds. Column 8, lines 37+. *Gerig, et al.* states that they provide a real time report of deviations between a reference position and the placement of a patient during each treatment. However, they do not teach a system which will provide real time indications of movement of the patient. Clearly, a patient could move significantly and return to the original position within five seconds and it would not be detected by the system of *Gerig, et al.* The claimed system, which determines position and tracks at the rate of 20 Hz has a fast enough response time that it can be used practically to determine if a patient has moved significantly during the treatment procedure so that the radiation beam, for instance, is not concentrated on the desired

target. It is also fast enough to indicate that movement of a patient was significant enough to distort images taken for instance during diagnosis. *Gerig, et al.*, using the much slower stereotriangulation approach is only capable of determining whether a patient has been positioned properly, but not whether movement which is out of the limits for treatment has occurred. Therefore, Claim 23 is patentable over *Gerig, et al.*

Claims 2-6 depend from Claim 23 and are therefore patentable over the reference for the same reasons.

Claims 7 and 19-21 were rejected under 35 USC as being unpatentable over *Gerig, et al.* in view of *Fujita* (USP 5,482,042).

Fujita is directed to apparatus which uses an ultrasonic detector to measure the respiration depth of a patient and includes a set of lights which provide feedback to the patient so that the patient can control breathing to a consistent depth during x-ray computer tomographic imaging. In this system, the patient takes a breath to expand the chest to a consistent position by observing the lights. This breath is then held while the x-ray images are being taken.

Claim 7 depends from Claim 22. As discussed above, *Gerig, et al.* does not render Claim 22 obvious. Claim 22 calls for a single camera to provide data to a processing means which provides three-dimensional tracking of the movement of a fiducial on the patient. *Fujita* adds nothing to the teachings of *Gerig, et al.* which would render Claim 22 obvious. As Claim 7 depends from Claim 22, it is patentable over any combination of *Gerig, et al.* and *Fujita.*

Claim 19 is an independent claim which calls for, *inter alia*, camera means generating digital signals and processing means comprising means determining movement of the patient from the digital image signals including movement associated with breathing by the patient, and gating means generating gating signals synchronized with the movement associated with breathing by the patient. *Fujita* teaches generating signals associated with patient breathing from direct measurement of chest position using an ultrasonic detection system. It does not suggest using digital images generated by a camera to detect breathing. *Gerig, et al.*, as mentioned, can only determine patient position at a repetition rate of five seconds, obviously too slow to detect breathing. Furthermore, there is nothing in

Gerig, et al. to suggest how the rhythmic movement associated with breathing could be extracted from a camera image. Accordingly, Claim 19 is patentable over any combination of *Gerig, et al.* and *Fujita*. Claims 20 and 21 depend from Claim 19 and are therefore patentable over the references for the same reasons. In addition, Claim 21 calls for the apparatus to be adapted for use during treatment with a radiation beam generated by a beam generator and wherein the gating means comprises means generating a gating signal synchronized to actuate the beam generator in synchronism with patient breathing. *Fujita* does not teach generating a gating signal synchronized to actuate the beam generator in synchronism with patient breathing. The signal generated by *Fujita* is a light signal indicating the relative expansion of the patient's chest. The patient observes the signals and establishes a desired level of expansion by reference to the lights. The patient then holds that chest position while the x-ray is separately operated. *Gerig, et al.* teaches nothing about synchronizing operation of a beam generated with breathing. Accordingly, Claim 21 further patentably distinguishes over the references.

Claims 8-14 were rejected over *Gerig, et al.* in view of *Hardy* (USP 5,398,684). *Hardy* describes a system useful for surgeons during stereotactic surgery. In this type of surgery, a given point in one modality image of a patient's brain is mapped onto the patient's brain images of several other modalities. For example, consider that a CT image shows a probe placed in the brain of a patient while the images generated by other modalities such as MRI, DSA, PET, NMR do not contain probe information. Given the CT image including probe location, *Hardy* determines the corresponding probe tip location in MRI. Image registration is accomplished by taking advantage of the fact that the stereotactive frame placed on the patient leaves unique fiducials in all modality images of the patient. Stereotactic surgery is essentially a blind surgical procedure. The *Hardy* system enhances the surgeons ability to conceptualize the position of a probe within the brain. It focuses on image registration and has nothing to do with motion detection. Column 8, lines 15-24 were cited for the proposition that one can rely on filtering schemes to provide boundary identification and that such recognition is tantamount to defining a template for "land mark" in or on the subject. Boundary identification is a different process from and is not "tantamount" to using a template to identify

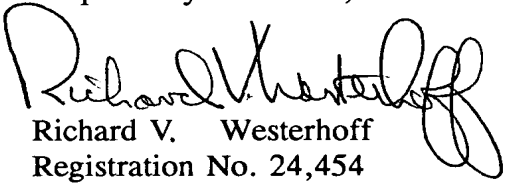
features in an image. Boundary identification looks for changes in gray scale values indicating boundary. Applicants use a template representing a feature to compare with various regions of the image to locate the feature.

As previously discussed, Claims 8-14 depend from Claim 22 which is directed to apparatus which uses a single camera to identify and provide three-dimensional tracking of the movement of fiducials. It has also been explained how *Gerig, et al.* does not teach such apparatus. *Hardy*, which is directed to registration of images, does not add anything to *Gerig, et al.* which would teach the three-dimensional tracking system of Claim 22.

Furthermore, Claim 8 calls for processing means repetitively applying multiple levels of filtering to determine successive positions of a fiducial. The types of filtering referred to at the cited passages in *Hardy, et al.* are not directed to feature identification but registration of the images. *Hardy* using filtering to make the two images look more alike so that they can be brought into registration. He teaches nothing about tracking movement of fiducials. Therefore Claim 8 further patentably distinguishes over the combination of references. Claims 9-11 set forth various types of filtering which can be used on the multiple levels to extract features from the images and therefore further patentably distinguish over the references. Claim 12 calls for using multiple levels of resolution to identify the positions of the fiducials and using multiple levels of filtering in each of the levels of resolution. Neither *Gerig, et al.* nor *Hardy* in any way suggest using multiple levels of resolution each with multiple levels of filtering to identify successive positions of fiducials. Therefore Claim 12 further patentably distinguishes over the references.

In view of all of the above, reconsideration and allowance of the application as now presented is respectfully solicited.

Respectfully submitted,



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